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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,963

12/03/2003

David Ernest Hartley

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9896 7590 12/22/2010

COOK GROUP PATENT OFFICE

P.O. BOX 2269

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

12/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,963	Applicant(s) HARTLEY ET AL.	
	Examiner RYAN J. SEVERSON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,9 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,9 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 6, 9 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brightbill (2003/0204245) in view of Cox et al. (5,824,040).**

Brightbill discloses a prosthesis comprising a graft-covered stent portion (120, see paragraph [0023]) comprising at least 3 stents (110) that are zig-zag shaped and self-expanding stainless steel or nitinol (see paragraph [0024]). The prosthesis also has an uncovered stent portion (140, see paragraph [0026]) being the same shape and material as the covered stents. However, Brightbill fails to disclose flexible links between the stents comprising threads or fibers.

3. Attention is drawn to Cox et al., who teach it is known to connect stents together with threads or fibers (see figure 7E) to increase the flexibility of the prosthesis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the weld links of Brightbill with the flexible thread links of Cox et al. to increase the flexibility of the Brightbill prosthesis.

4. Further regarding claim 24, the combination of Brightbill and Cox et al. does not disclose 8-10 uncovered stents. However, Examiner holds this is merely an obvious matter of design choice. A person having ordinary skill in the art would have recognized

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that the uncovered stent portion could be created with more than two uncovered stents to be able to increase the effective treatment length of the prosthesis. A person having ordinary skill in the art would have recognized that the number of uncovered stents in the prosthesis is not critical to the invention. Therefore, Examiner holds it would have been obvious to one having ordinary skill in the art at the time the invention was made to have created the prosthesis of Brightbill with 8-10 uncovered stents instead of two for the purpose of creating a longer prosthesis that is capable of treating a longer section of damaged vessel. See paragraphs 10 and 11 below for further explanation.

5. Regarding claim 6, the combination of Brightbill and Cox et al. does not disclose the knot holding the threads to the stents. However, Examiner asserts the use of a specific knot would have been obvious to one of ordinary skill in the art at the time the invention was made to secure the graft to the stent.

6. **Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brightbill (2003/0204245) in view of Cox et al. (5,824,040) as applied to claim 24 above, and further in view of McNamara et al. (6,004,347).** The combination of Brightbill and Cox et al. fails to disclose barbs extending from the stent through the graft. Attention is drawn to McNamara et al., who teach a graft disposed on the outside of a stent with a barb penetrating through the graft (see figures 10 and 11) to hold the graft onto the stent and to more securely anchor the stent against the vessel wall when deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used barbs on the stents of the combination of

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Brightbill and Cox et al. in the manner taught by McNamara et al. to hold the graft onto the stent and to more securely anchor the stent against the vessel wall when deployed.

Response to Arguments

7. Applicant's arguments filed 10/6/2010 have been fully considered but they are not persuasive.

8. As an initial matter, it appears applicant is making arguments that have already been proven not persuasive and categorically incorrect. For example, applicant has decided to once again argue the teachings of Brightbill do not support an interpretation of a graft material covering some, but not all, of the stents. This argument was addressed in the advisory action mailed 6/1/2010. Therefore, it appears applicant is merely unnecessarily delaying prosecution by bringing back arguments that were already addressed.

9. The disclosure of Brightbill could not be clearer. It states that "In such embodiments the sheath or other delivery matrices **would be disposed on only a portion of the length of the stent.**" It is unclear to the Examiner how applicant can take any position that Brightbill teaches away from this idea when an explicit statement exists within the disclosure at paragraph [0023], which applicant even recited to the Examiner in the present response. The "sheath" that Brightbill refers to is analogous to the claimed graft. Examiner once again encourages applicant to review the disclosure of Froix 6,016,789, which Brightbill references in paragraph [0023] as showing sheath wrapped stents.

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10. Examiner also maintains that applicant has not shown any criticality for having 8-10 uncovered stents, and absent any criticality, Examiner will hold this limitation to have been obvious as set forth above and as described in detail in the non-final rejection mailed 7/7/2010 (at paragraphs 10 and 11).

11. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. So long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

12. Examiner also respectfully disagrees with applicant's assertion that the disclosure of Brightbill is only applicable to balloon expanding stents. Brightbill explicitly discloses the stent maybe self expanding (see paragraph [0044]). Therefore, in view of this explicit disclosure from Brightbill, Examiner can find no reason why a skilled artisan would think the stents of Brightbill are only balloon expandable. It is clear after reviewing this argument that applicant has not read the entire Brightbill disclosure.

13. Applicant also makes a statement that there is no suggestion or requirement in Brightbill to link stents. However, Examiner never suggested linking stents. Examiner suggested *replacing* the welds of Brightbill with the flexible links of Cox et al. to increase the overall flexibility of the device. Skilled artisans certainly would understand that having a stent with increased flexibility would be advantageous.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN J. SEVERSON whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan J Severson/
Examiner, Art Unit 3731
12/16/10

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773